



Transmittal Letter
Page 1 of 1

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AF

In The United States Patent and Trademark Office

In re application of: James P. Elia

Group No.: 1646

Serial No.: 09/064,000

Examiner: Elizabeth C. Kemmerer, Ph.D.

Filed: April 21, 1998

For: METHOD FOR GROWTH OF SOFT TISSUE

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: DIRECTOR OF GROUP 1600

1. Transmitted herewith is a Petition to Director of Group 1600 for this application.
2. Applicant is a small entity.
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Reg. No.: 26,611


Signature of attorney

Gerald K. White

Type or print name of attorney

Tel. No.: (312) 920-0588

GERALD K. WHITE & ASSOCIATES, P.C.
205 W. Randolph Street, Suite 835
Chicago, IL 60606
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: James P. Elia)
Serial No.: 09/064,000) Group Art Unit: 1646
Filed: April 21, 1998) Examiner: Elizabeth C. Kemmerer, Ph.D.
For: METHOD FOR GROWTH)
OF SOFT TISSUE)

PETITION UNDER 37 C.F.R. §1.113 TO DIRECTOR OF GROUP 1600

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

This Petition is filed under 37 C.F.R. §1.113 seeking review and resolution of the Examiner's objection to claims 382-388, all the claims in the subject application. Petitioner prays for relief in the form of the withdrawal of such objection and the issuance of a complete action on the merits of the invention of claims 382-388.

BASIS FOR PETITION

Petitioner believes that the Director's review of Examiner's objection to claims 382-388 is justified based upon the Examiner's misunderstanding of Petitioner's invention, which is manifested by the Examiner's mischaracterization and lack of understanding of the terms "living organism," "multifactorial," and "nonspecific" as they relate to the claimed invention.

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The Examiner's entering of claims 382-388, and then effectively not examining the subject matter of such claims, renders it difficult, if not impossible, to respond to the Examiner's final rejection. The Examiner erred procedurally by treating the newly entered claims as if these claims were drawn to subject matter contained in canceled claims. Petitioner believes that any appeal to the Board of Patent Appeals and Interferences would necessarily raise jurisdictional issues and result in a remand for clarification of the status of claims 382-388. Accordingly, resolution of the objection by the Director of Group 1600 is a prerequisite to the further, meaningful prosecution of the instant application.

STATUS OF THE APPLICATION

Claims 382-388 (attached hereto as Exhibit A) are the only claims pending in the subject application. These claims were first presented in Petitioner's response of August 18, 2004, and were entered by the Examiner. In the Examiner's October 18, 2004 Final Office Action, these claims were finally rejected on technical grounds and also were objected to for allegedly reading upon non-elected inventions. The Examiner did not enter a prior art rejection against any claim. Petitioner believes that the Final Rejection is premature because no action, let alone a first action, was made on the merits of the subject matter of claims 382-388.

PROSECUTION HISTORY OF THE APPLICATION

The first action on the merits for the instant application was a rejection issued by Examiner Nicholas D. Lucchesi on May 27, 1999. Following Petitioner's response filed December 16, 1999, Examiner Lucchesi issued a non-Final Rejection on August 16, 2000. Petitioner responded to such rejection in an Amendment dated February 14, 2001. Examiner Lucchesi did not respond to this Amendment and instead is believed to have transferred

jurisdiction of the application to Examiner Elizabeth C. Kemmerer sometime during the summer of 2003. The two and one-half year period of inaction while the case was under Examiner Luccehs's jurisdiction included a six-month suspension of prosecution. On September 15, 2003, Examiner Kemmerer acted on the application for the first time by making a 26-way restriction requirement on previously cancelled claims. Petitioner responded to such restriction requirement on September 18, 2003 by pointing out that the claims subject to the restriction requirement had been canceled and submitted a copy of the Amendment containing the pending claims. On November 19, 2003, the Examiner vacated the September 15, 2003 restriction requirement and made a two-part species restriction. Petitioner elected the species drawn to organic matter in the response of December 17, 2003. In the February 24, 2004 action, the Examiner withdrew the original restriction requirement because of an apparent lack of understanding of the term "organic matter." The Examiner erroneously believed that organic matter was "limited to small organic molecules, such as ring structures and not encompassing species listed in the requirement, such as the growth factor polypeptides of species d) – n)." Petitioner remains at a loss to understand how such an interpretation could have been placed on the term "organic matter" because no such ring-type structure was disclosed in the specification. Moreover, Petitioner does not understand how the Examiner could determine that polypeptides are not organic matter. On March 3, 2004, Petitioner elected to prosecute claims to the sub-generic term or species, "living organism." Petitioner also identified claims readable on such inventions as including claims to multifactorial and/or nonspecific living organisms. Multifactorial and/or nonspecific are disclosed in the specification as characteristics of growth factors comprising cells, such as stem cells. Please see page 37, lines 19-25 and page 49, line 28 through page 50, line 6. In a subsequent Office Action dated June 3, 2004, the Examiner changed the restriction requirement yet another time by joining species o) –bacteria and species q) –virus into species c)

-living organism and then rejected all of the claims under 35 U.S.C. §101 and §112. During such rejection, the Examiner contended that the terms “multifactorial” and “nonspecific” were not used to describe living organisms in the art and that a living organism included bacteria and virus or any other living organism which promotes tissue growth and that a stem cell is not a living organism. Thus, in the Office Action the Examiner excluded an embodiment (multifactorial and nonspecific growth factor, such as a stem cell) of the disclosed invention that was elected by Petitioner. Petitioner responded to the June 3, 2004 Office Action on August 19, 2004 by pointing out the Examiner’s erroneous understanding of the above terms and, in an effort to obtain a first action on the merits of its elected invention, canceled the prior claims and presented a new set of claims. Petitioner’s responses (amendments) have consistently constituted a narrowing from the original growth factor genus while staying within the scope of the elected invention. Petitioner expected that such submissions would provoke a legitimate action on the merits. Instead, the Examiner issued the Final Rejection on October 18, 2004, which basically repeated the errors of the previous Office Action.

Including Examiner Lucchesi’s inaction and six-month suspension and Examiner Kemmerer’s procedural Office Actions that involve primarily restriction requirements, rather than actions on the merits, over three and one-half years have passed since the last Office Action on the merits was issued. The three-year term extension guarantee, which applies to later-filed applications, does not apply to the instant application because Petitioner’s April 21, 1998 filing date falls between June 8, 1995, and May 28, 2000. Thus, perforce, Petitioner has already been severely prejudiced in term length by the long administrative delay by the PTO between the February 15, 2001 response and the Office Action of October 18, 2004. Furthermore, this delay has been compounded by the outstanding Final Rejection, which does not appear to treat the elected invention.

EXAMINER'S OBJECTION TO CLAIMS 382-388

In objecting to claims 382-388, the Examiner stated that the claims read on non-elected inventions. As will be demonstrated below, the claims, in fact, read upon the invention elected by Petitioner; and the Examiner's position is flawed due to a fundamental lack of understanding of and a mischaracterization of the terms "multifactorial" and "nonspecific" as well as "living organism." Petitioner believes that the Examiner's objection is inextricably linked to a series of restriction requirements and a failure of the Examiner to consider the written disclosure when reviewing the claims for compliance with the requisite patent regulations and statutory requirements.

At page 37, lines 19-25 and at page 49, line 28 through page 50, line 6 of the specification, it is clear that the terms "multifactorial" and "nonspecific" are utilized as adjectives to characterize growth factors, such as stem cells. This fact is included in the Fifth Supplemental Information Disclosure Statement ("IDS") filed October 21, 2004, (attached hereto as Exhibit B), which crossed in the mail with the October 18, 2004 Final Rejection. It is beyond reasonable dispute that one reading the dictionary references in the IDS would conclude that "multifactorial" and "nonspecific" are adjectives denoting characters and qualities of cells.

The Examiner, in the Final Rejection, alleged that the art only uses such terms to describe causes, effects, and processes. Obviously, such allegation flies in the face of conventional medical terminology. These terms are used throughout Petitioner's specification in a manner consistent with the definitions contained in Exhibit B. The Examiner's erroneous understanding of these terms goes to the core of the issue as to whether or not the present claims are embraced by the elected invention.

The Examiner's second major technical misunderstanding is in alleging that stem cells are not living organisms. In fact, the Examiner stated at page 6 of the Final Rejection that,

“While Petitioner may be his own lexicographer, to define a living organism as encompassing stem cells is repugnant to the meaning of ‘living organism’ found in the art. Such is improper.” The Examiner also alleged that, “...the art defines ‘living organism’ as independent,” and that, “Stem cells are part of a living organism, but are not living organisms, per se.” All of the above allegations are factually incorrect and at variance with accepted usage in the medical arts to which the present invention is directed. What we have here is a case where the Examiner chose to become her own lexicographer rather than simply considering such terms in light of Petitioner’s specification and highly reputable medical publications.

In the Response of August 18, 2004, Petitioner provided evidence that cells are living organisms. That stem cells are clonogenic and clones are living organisms are such well-established biological tenets, that official notice should be taken of these facts. In any event, clonogenic means the cells generate identical copies of themselves. Based on the aforesaid information cited in the Response, it is irrefutable that cells, including stem cells, are living organisms. The Examiner responded to this statement by agreeing that the term “clone” can refer to pieces of nucleic acid, cells, or entire living organisms but did not accept this evidence on the basis that cells, while alive, are not necessarily a living organism. The Examiner further stated that living organisms must be independent. In addressing this issue, the Examiner admits the well-established fact that cells are clones. If clones are living organisms, cells must also be living organisms because cells routinely clone. Moreover, the On-line Medical Dictionary published at the Dept. of Medical Oncology, University of Newcastle upon Tyne (attached hereto as Exhibit C) includes the following definition:

Clone – a propagating population of organisms, either single cell or multicellular, derived from a single progenitor cell. Such organisms should be genetically identical, though mutation events may abrogate this.

Obviously, from this definition, a living organism can consist of a single cell.

In any event, the glossary posted on the Biospace website, www.biospace.com (attached hereto as Exhibit D), contains a definition of “cell” provided by the National Institutes of Health and demonstrates that a single cell is a living organism. The definition is as follows:

Cell – it is a small, watery membrane-bound compartment filled with chemicals and a complete copy of the organism’s genome. All living organisms are made of one or more cells.

The above definitions clearly evince that the Examiner’s narrow definition of “living organism” is contrary to knowledge understood in the medical arts.

The Examiner has patently mischaracterized the nature and meaning of the well-recognized medical terms “multifactorial,” “nonspecific,” and “living organism.” The Examiner’s multifarious restriction requirements based upon technically inaccurate information have further prolonged prosecution and are tantamount to denying Petitioner procedural due process. Giving the above terms their correct medical meaning, it is clearly evident that claims 382-388 fall within Petitioner’s elected invention and that an action examining such claims should have been provided by the Examiner. Petitioner believes that it is entitled to a full, complete action on the merits of such claims.

In view of the above remarks and evidence, Petitioner hereby respectfully requests the following relief:

1. The Examiner be instructed to withdraw the objection to claims 382-388;
2. The Examiner be instructed to construe the restriction requirement in light of Petitioner’s specification and in accordance with conventional medical terminology and thereby construe Petitioner’s elected specie to include claims 382-388;

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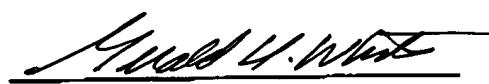
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PATENT APPL. NO. 09/064,000

3. The Examiner be instructed to withdraw the Final Rejection as being premature and issue a new, non-final action on the merits for claims 382-388; and
4. Petitioner respectfully requests an oral hearing to further address this matter. It is suggested that Petitioner's attorneys, Gerald K. White and Charles N. Lovell, attend any hearing, along with Examiner Elizabeth C. Kemmerer, Ph.D., and the Supervising Primary Examiner, Brenda Brumback, Ph.D. Petitioner believes that a hearing could serve to place the application on track and also expedite its prosecution. This objective is especially important to Petitioner in view of the above-discussed term erosion situation.

Respectfully submitted,

Date: November 4, 2004



Gerald K. White
Reg. No. 26,611
Attorney for Petitioner

Date: November 4, 2004



Charles N. Lovell
Reg. No. 38,012
Attorney for Petitioner

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382. A method for producing a desired soft tissue in a body of a human patient comprising:

- (a) Placing cells in said body of said human patient;
- (b) Forming a bud in said body of said human patient; and
- (c) Growing said desired soft tissue from said bud.

383. The method of claim 382, wherein said cells are multifactorial and non-specific.

384. The method of claim 383, wherein said cells comprise stem cells.

385. The method of claim 382 further comprising forming a new artery.

386. The method of claim 383 further comprising forming a new artery.

387. The method of claim 382, wherein said soft tissue comprises mesodermal tissue.

388. The method of claim 382, wherein said soft tissue comprises an artery.

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ASSOCIATES
Charles N. Lowell, Esq.* - Patents
Henry W. Tarrington, Esq.* - Patents
*Member of Virginia Bar

Business Associate
Karen D. Allen - Trademarks

FACSIMILE COVER SHEET

DATE: October 21, 2004

NO. OF PAGES: 7

TO: Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Examiner Elizabeth Kemmerer, Ph.D.
Art Unit 1646

FAX NO.: (703) 672-9306

FROM: Gerald K. White

RE: Patent Application Serial No. 09/064,000
Applicant: James P. Elias
Filed: April 21, 1998
Title: METHOD AND APPARATUS FOR
INSTALLATION OF DENTAL IMPLANT

Sir:

Enclosed is Applicant's Fifth Supplemental Information Disclosure Statement (including Certification), Form PTO-1448 (Modified), and a copy of each publication listed thereon (References ABY and ABZ).

Respectfully submitted,


Gerald K. White
Reg. No. 26,811
Attorney for Applicant

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ASSOCIATES

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Henry W. Tarring, Esq.* - Patents

*Member of Virginia Bar

BUSINESS ASSOCIATE

Karen D. Allen - Trademarks

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DATE: October 21, 2004 **NO. OF PAGES:** 7

TO: Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Examiner Elizabeth Kemmerer, Ph.D.
Art Unit 1646

FAX NO.: (703) 872-9306

FROM: Gerald K. White

RE: Patent Application Serial No. 09/064,000
Applicant: James P. Elia
Filed: April 21, 1998
Title: METHOD AND APPARATUS FOR
INSTALLATION OF DENTAL IMPLANT

Sir:

Enclosed is Applicant's **Fifth Supplemental Information Disclosure Statement** (including Certification), Form PTO-1449 (Modified), and a copy of each publication listed thereon (References ABY and ABZ).

Respectfully submitted,



Gerald K. White

Reg. No. 26,611

Attorney for Applicant

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PATENT
Appl. No. 09/064,000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: James P. Elia)
Serial No.: 09/064,000) Group Art Unit: 1646
Filed: April 21, 1998) Examiner: Elizabeth Kemmerer, Ph.D.
For: METHOD AND APPARATUS)
FOR INSTALLATION OF)
DENTAL IMPLANT)

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

Enclosed herewith, please find Form PTO-1449 (Modified) pertaining to the above-identified application. A copy of each of the publications listed thereon (References ABY-ABZ) is enclosed.

This Fifth Information Disclosure Statement (IDS) is submitted to address an issue raised by the Examiner regarding the meaning of the terms "multifactorial" and "nonspecific cells." While Applicant believes that it has used such terms properly and that one skilled in the art would fully comprehend the meaning of such terms, dictionary definitions are included to further acquaint the Examiner with such terms as they are used in the medical arts.

As will be noted from References ABY and ABZ, "multifactorial" and "nonspecific" are adjectives that denote qualities and characterizations of cells.

“Multifactorial” means: “involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)”

“Nonspecific” means: “...undestined, undetermined, undifferentiated,...”

It is clear from a reading of the patent application, the qualities and characteristics of multifactorial and nonspecific cells can be found in cells such as: stem cells, germinal cells, and pluripotent cells.

No one skilled in the art would question that a fundamental property of all of these cells is that they are undifferentiated.

Also, no one skilled in the art would question that the state of being known as “pluripotent” permits a cell to be capable of affecting more than one organ or tissue. A cell’s capability to affect more than one tissue or organ involves or depends upon several factors or causes and can result from the interaction of many genes.

This IDS is being submitted in an effort to reduce the number of issues in the instant application and thereby expedite the prosecution thereof.

No fee is believed to be due because Applicant and Applicant’s attorney were not aware of such patent more than three (3) months prior to this submission. A certification including such facts is enclosed.

Respectfully submitted,

Date: October 21, 2004



Gerald K. White
Reg. No. 26,611



PATENT
Appl. No. 09/064,000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: James P. Elia)
Serial No.: 09/064,000) Group Art Unit: 1646
Filed: April 21, 1998) Examiner: Elizabeth Kemmerer, Ph.D.
For: METHOD AND APPARATUS)
FOR INSTALLATION OF)
DENTAL IMPLANT)

CERTIFICATION

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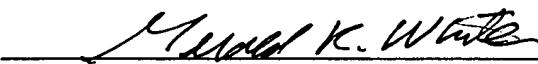
Sir:

I, Gerald K. White, Attorney for Applicant, hereby state that the two references cited in this Fifth Supplemental Information Disclosure Statement ("IDS") were first discovered by me less than three (3) months prior to the date set forth below.

I further state that no item of information contained in this Fifth Supplemental IDS was cited in a written communication from a foreign patent office in a counterpart foreign application, and, to my knowledge, after making reasonable inquiry, no item of information contained in this Fifth Supplemental IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three (3) months prior to the filing of this statement.

Respectfully submitted,

Date: October 21, 2004


Gerald K. White
Reg. No. 26,611

**List of Patents and Publications For
Applicant's 5th Supplemental Information Disclosure Statement**

Page 1 of 1

Form PTO-1449 (Modified)
(Use several sheets if necessary)

Docket No.:

Serial No. : 09/064,000

Group No.:

1646

Filing Date: April 21, 1998

Examiner

Elizabeth Kemmerer, Ph.D.

Applicant: James P. Elia

Oct 20 04 05:49p

Winfield

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What does multifactorial mean?

multifactorial adj : involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)

Source: WordNet (r) 2.0

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p . 3



What does nonspecific mean?

nonspecific adj : not caused by a specific agent; used also of staining in making microscope slides; "nonspecific enteritis" [ant: specific, specific]

Source: WordNet (1) 2.0

58 Moby Thesaurus words for "nonspecific": abstract, aleatoric, aleatory, amorphous, bland, blobby, blurred, blurry, broad, chance, chancy, chaotic, collective, confused, disordered, featureless, foggy, fuzzy, general, generalized, generic, hazy, hit-or-miss, ill-defined, imprecise, inaccurate, inchoate, incoherent, indecisive, indefinable, indefinite, indeterminate, indeterminable, indistinct, inexact, lax, loose, nebulous, neutral, obscure, orderless, random, shadowed forth, shadowy, shapeless, stochastic, sweeping, unchartered, undefined, undetermined, undifferentiated, undifferentiated, unplain, unspecified, vague, veiled, wide

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clone from On-line Medical Dictionary

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clone

<cell biology> A propagating population of organisms, either single cell or multicellular, derived from a single progenitor cell. Such organisms should be genetically identical, though mutation events may abrogate this.

(18 Nov 1997)

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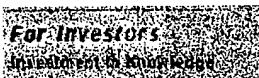
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